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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/805,239 | 03/14/2001 | Maximilian Angel | 51248 | 2124 |

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KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

JOYNES, ROBERT M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1615

DATE MAILED: 11/20/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,239

Applicant(s)

ANGEL ET AL.

Examiner

Robert M. Joynes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-24 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) 17, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-24 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment filed on August 13, 2002.

Double Patenting

Claims 1-16, 18-24 and 27-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-5, 10-13, 15-21 and 23-25 of copending Application No. 09/811542. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a capsule composition. The difference being only that one is deemed a soft capsule and the other deemed a hard capsule. No other distinction is seen between the claims. The same polymers and additional components are used in the same concentration ranges. Therefore, the claims are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12, 15, 16 18, 19, 21 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 922457 (hereinafter '457) in view of Harreus et al. (US 3984494). '457 teaches a graft copolymer wherein vinyl esters and ester of acrylic or methacrylic acid can be produced on polyalkylene oxides (Page 1, lines 55-69; Claim 1). The monomers of the invention can be used alone or in admixture with one another (Page 2, lines 33-48). These graft copolymers are known to be formed into films with plasticizers (Page 4, lines 22-30). '457 does not expressly teach that the polymers are formed into capsules.

Harreus et al. teach a capsule comprising polyvinyl alcohol, vinyl acetate and polyethylene oxide (Col. 1, lines 38-47; Col. 2, Example 1; Col. 3, Claim 1). The polyvinyl alcohol is present in the capsule in amounts from 20% to 98% (Col. 1, lines 38-47; Col. 3, Claim 1). The vinyl acetate is present in the capsule in amounts from 1% to 50% (Col. 1, lines 38-47; Col. 3, Claim 1). The polyethylene oxide is present in the composition in amounts from 1% to 50% (Col. 1, lines 38-47; Col. 3, Claim 1). The capsule further comprises a plasticizer (Col. 1, lines 58-68). The plasticizer is glycerol, sorbitol, cane sugar or propylene glycol (Col. 1, lines 58-68).

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is

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critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare capsules from the polymers of '457.

One of ordinary skill in the art would have been motivated to do this to prepare improved capsules that are nearly not susceptible to attacks by microorganisms and that can be sterilized easily (Harreus, Col, 2, lines 8-11).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 922457 (hereinafter '457) in view of Harreus et al. (US 3984494) further in view of Ishii et al. (US 5965651). The teachings of '457 and Harreus are discussed above. Neither reference teaches using a crosslinking agent.

Ishii teaches the incorporation of crosslinking agents in polymer used to prepare molded articles (Col. 2, lines 25-55). Examples of the crosslinking agents include boric acid and dicarboxylic acids (Col. 5, lines 29-63).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate a crosslinking agent in the graft copolymer of '457.

One of ordinary skill in the art would have been motivated to do this to retain the shape of the molded polymeric article (Ishii, Col. 5, lines 44-50).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 20, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 922457 (hereinafter '457) in view of Harreus et al. (US 3984494) further in view of Cade et al. (WO 9827151). The teachings of '457 and Harreus are discussed above. Neither reference teaches what the finished capsules are filled nor do they teach an additional coating on the capsule.

Cade teaches a polymer capsule comprising a water-soluble cellulose ether, a hydrocolloid and a sequestering agent (Page 9, Claim 1). The sequestering agent can be boric acid (Page 3, lines 16-20). The capsule further comprises a coloring agent (Page 4, lines 12-21). Cade et al. teach that the capsule can be coated with a suitable coating agent (Page 4, line 22 – Page 5, line 2). The coating agent can be cellulose acetate phthalate, polyvinyl acetate phthalate, methacrylic acid polymers, hypromellose phthalate, hydroxypropylmethyl cellulose phthalate or hydroxyalkyl methyl cellulose phthalate (Page 4, line 22 – Page 5, line 2). Cade further teaches that the capsules can be filled with agrochemicals, seeds, herbs, foodstuffs, dyestuff, pharmaceuticals, flavoring agents and the like (Page 5, lines 3-5).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include in a polymeric capsule composition a gastric resistant coating and a filling such as a pharmaceutical.

One of ordinary skill in the art would have been motivated to do this to prepare a capsule with various color schemes for identification of active ingredient purposes. One

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of ordinary skill in the art would be motivated to add a coating to the capsule to prepare capsules of differing release profiles, for example a sustained released capsule. One would be motivated to fill the capsule with various components to facilitate effect delivery of that component.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 1-16, 18-24 and 27-30 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner would like to point out that the term "soft capsule" is a relative term. The term "soft capsule" is not defined by the claim and there is no reference point from which to ascertain what a soft capsule would be. No criticality is seen in this particular term.

Conclusion

Due to the new grounds for rejection, this action is deemed non-final.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
November 15, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600